

Nationwide Health Information Network

NHIN Coordinating Committee

SUBJECT: NHIN CHANGE PROCESS – PERFORMANCE AND SERVICE SPECIFICATIONS		
STATUS: APPROVED by NHINCC and Participants	POLICY #: NHIN-CC: 4	
Date Approved: 7/15/2010	Version: 2.0	Page 1 of 9

I. Purpose

Changes to Performance and Service Specifications will occur as the NHIN continues to evolve. The purpose of this Operating Policy and Procedure is to describe the process by which the NHIN Coordinating Committee will evaluate the development of new, or modification of existing, NHIN Performance and Service Specifications and Emergent Specifications to determine whether they would result in a Material change to the Performance and Service Specifications. The NHIN Technical Committee and the NHIN Coordinating Committee are committed to working together collaboratively to create an efficient and effective Change Process for the production NHIN Exchange environment. This Policy addresses the NHIN Coordinating Committee's role in the Change Process. The Policy addresses three distinct areas.

A. Requests for Consultation with NHIN Technical Committee.

In contemplation of changes to the Performance and Service Specifications or use of Emergent Specifications in the production environment, the NHIN Technical Committee may desire input from the NHIN Coordinating Committee regarding the impact and considerations for Materiality or other effects of such changes on the Participants and the operation of the NHIN Exchange before a change is formally submitted to the NHIN Coordinating Committee for evaluation. In such cases, the NHIN Technical Committee may submit a request for consultation to the NHIN Coordinating Committee (a "Request for Consultation").

B. Development Changes. *The Participants have granted the NHIN Technical Committee the authority to adopt new NHIN Performance and Service Specifications and use of Emergent Specifications), and to adopt amendments to, or repeal and replace, the NHIN Performance and Service Specifications (collectively a "Development Change"). The exact process to be followed in the adoption of a Development Change depends on whether it is Material or non-Material. The NHIN Coordinating Committee is charged with determining Materiality with regard to a Development Change.*

C. Compliance Changes. *The Participants have granted the NHIN Technical Committee the authority to adopt new, or to make changes to existing, NHIN Performance and Service Specifications that are necessary for: (i) compliance with Federal law; or, (ii) to maintain the stability of the NHIN (collectively a "Compliance Change"). The NHIN Technical Committee is required to seek input from the NHIN Coordinating Committee prior to implementing a Compliance Change.*

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II. Policy

The NHIN Coordinating Committee delegates to ONC (and through its Cooperative Agreement with NeHC) the power to receive Changes from the NHIN Technical Committee to be evaluated under this policy and to help coordinate Requests for Consultations between the Committees.

For Development Changes, the NHIN Coordinating Committee shall evaluate whether the change is Material as defined in the DURSA and communicate that determination to the NHIN Technical Committee.

For Compliance Changes, the NHIN Coordinating Committee shall evaluate the Change and provide comments to the NHIN Technical Committee.

Before the NHIN Technical Committee adopts Emergent Specifications for use in the production environment or formally submits Changes to the NHIN Coordinating Committee for evaluation, the NHIN Technical Committee may seek preliminary input from the NHIN Coordinating Committee in the form of a Request for Consultation.

The NHIN Coordinating Committee requests that the NHIN Technical Committee submit all Changes and Requests for Consultation with sufficient explanatory information about the proposed Change which will allow the Coordinating Committee to determine whether the proposed Change is Material or to provide the Technical Committee with meaningful feedback in response to its Request for Consultation. What constitutes “sufficient explanatory information” will vary depending upon the nature of the proposed Change. The Coordinating Committee will work with the Technical Committee to develop agreed upon parameters and may consult with ONC as it deems necessary and appropriate.

The NHIN Coordinating Committee may submit the any proposed Change or Request for Consultation to legal counsel as it deems necessary and shall do so if changes may require amendments to legal agreements or if legal impact needs to be assessed.

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III. Procedure

A. Receipt.

All Changes and Requests for Consultation will be directed to the NeHC (insert e-mail address) in writing. The NHIN Coordinating Committee requests that when the NHIN Technical Committee submits a Change or Request for Consultation, it provides sufficient information for the NHIN Coordinating Committee to properly evaluate the Change or Request for Consultation. The NHIN Technical Committee may include the following information in its submission of Changes or Requests for Consultation and/or such other information deemed reasonably necessary for the NHIN Coordinating Committee to formulate a proper response:

1. The type of the proposed change (e.g. new, amendment, repeal)
2. The name and version number of the specification;
3. Whether the proposed change is a Development Change, Compliance Change or a Request for Consultation;
4. A date upon which the NHIN Technical Committee would like a response;
5. A brief description of the reasons for the proposed change (e.g. to enhance metadata available about a document, to meet requirements of a new use case or to comply with a specific law or regulation);
6. A description of the actual changes;
7. A preliminary analysis of the potential business and technical impact to Participants and end users; and
8. A copy of the specification.

NeHC is requested to catalog all Changes and Requests for Consultation upon receipt. The log shall contain the date of receipt; the type of Change (e.g. new, amendment, repeal); the name and version number of the specifications affected; whether it is a Request for Consultation, Development Change, Compliance Change; a date upon which the NHIN Technical Committee would like a response; and, a brief description of the reasons for the Change or Request for Consultation (e.g. to enhance metadata available about a document, to meet requirements of a new use case or to comply with a specific law or regulation).

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B. Evaluation

The NHIN Coordinating Committee shall, within a reasonable timeframe after being informed of NeHC's receipt of a Change or Request for Consultation, forward the Change or Request for Consultation to a task group designated by the NHIN Coordinating Committee to consider the NHIN Technical Committee's request and make a recommendation for action to the NHIN Coordinating Committee. During consideration of the Change or Request for Consultation, the task group may request additional information regarding the Change or Request for Consultation or discuss the Change or Request for Consultation with the NHIN Technical Committee, as the task group deems reasonably necessary.

Evaluation Criteria for Requests for Consultation

If the NHIN Technical Committee submits a Request for Consultation, the task group shall evaluate that request and make a recommendation to the NHIN Coordinating Committee using the following criteria:

- (i) Would the proposed change be Material and, if so, in what respects may it be Material?
- (ii) Does the proposed change require the collection, use, or exchange of data elements not supported by organizations represented on the NHIN Coordinating Committee?
- (iii) Does the proposed change enhance, conflict with, or hamper other business operations or capabilities of organizations represented on the NHIN Coordinating Committee?
- (iv) Will the proposed change provide essential exchange capabilities needed in the marketplace?

The task group will present its findings and recommendations on the Request for Consultation to the NHIN Coordinating Committee within five (5) weeks of the task group receiving the Request for Consultation. The NHIN Coordinating Committee will review the findings and recommendations from the task group and make a final determination. It will forward its determination to the NHIN Technical Committee in accordance with Section C.

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Evaluation Criteria for proposed Changes

1. *Evaluation of Development Changes.* If the change is a Development Change, the NHIN Coordinating Committee shall ensure each Participant is provided all information originally submitted by the NHIN Technical Committee for evaluation and has the opportunity to respond either verbally or in writing to the NHIN Coordinating Committee by a designated response date with the following information:
 - a. Will implementation of the Development Change have a significant adverse operational or financial impact on the Participant;
 - b. Will implementation of the Development Change require the Participant to materially modify its existing agreements with its Participant Users or third parties;
 - c. Does the Participant believe that implementation of the Development Change will require an amendment to the DURSA, including amendments to the Permitted Purposes.
 - d. Indicate whether the Participant would implement a change (if optional).

This responsibility may be fulfilled by providing the information to the Participant's representative on the NHIN Coordinating Committee.

The Participant must provide supporting reasons or rationale for each response where the Participant responds in the affirmative, which indicates the change may be Material. The task group or the NHIN Coordinating Committee may request additional information from Participants consistent with Policy # NHIN-CC: 6, Information Handling, to further evaluate the responses. Participants are strongly encouraged to make a representative available to answer questions about the Participants responses.

Requests of and responses from Participants as provided in this policy may be by formal written response or by verbal communication, either in person by conference call, electronic mail or other means as long as clear written records of the requests and responses are maintained.

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The task group will review responses from the Participants to inform its recommendation to the NHIN Coordinating Committee on the materiality of the Development Change. The definition of “Material” in the DURSA includes changes that:

- (i) have a significant adverse operational or financial impact on at least 20% of Participants;
- (ii) require at least 20% of Participants to materially modify their existing agreements with Participant Users or third parties; or
- (iii) require an amendment to the DURSA. In determining whether a Development Change is “Material,” the task group will rely on the responses received from the Participants as of the designated response date.

In addition, the task group will consider the implications to the policies and procedures for the NHIN Exchange.

Participants who do not submit responses by that date are deemed to have answered “no” to each question in 1(a)-(c) above. For the purpose of calculating whether the 20% thresholds are met, the task group should base the total number of Participants on the number of Participants on the designated response date.

If a new organization becomes a Participant after Participants have been asked to respond to questions about the Development Change but before the designated response date, this new Participant shall be given an opportunity to respond by the designated response date.

The task group will present its recommendation to the NHIN Coordinating Committee at the NHIN Coordinating Committee’s next regularly scheduled meeting following the designated response date. The NHIN Coordinating Committee will review the task group’s recommendation and make a final determination regarding whether the Development Change is “Material.” It will forward its determination to the NHIN Technical Committee in accordance with Section C.

2. *Evaluation of Compliance Changes.* If the change is a Compliance Change, the task group will review the change to assess its impact. The task group will present its findings and recommendations on the Compliance Change to the NHIN Coordinating Committee within two (2) weeks of the task group receiving the Compliance Change. The NHIN Coordinating Committee will review the findings and recommendations from the task group and determine the input it will provide to the NHIN Technical Committee. It will forward its input to the NHIN Technical Committee in accordance with Section C.

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3. *Evaluation of the Timeline for Implementation of the Change.* For both Development Changes and Compliance Changes, the task group will assess and make recommendations to the NHIN Coordinating Committee on the timeline for implementing the Change including, but not limited to, the number of prior versions of the Specification that should be supported and the amount of time that Participants should be given to migrate to the new Specification. The task group will consider:
- Whether the Change impacts interoperability among the Participants;
 - The number of versions of the Specification that will be supported for backward compatibility purposes and the business implications of such support;
 - If multiple versions will be supported, a sunset date for such support;
 - The business implications for Participants related to migrating to the new Specification;
 - The number of Participants and number of transactions that will be impacted by the new Specification; and
 - The amount of time that Participants should be given to migrate to the new Specification.

The task group will present its recommendations regarding implementation to the NHIN Coordinating Committee at the same time it presents its other recommendations regarding the same Change to the NHIN Coordinating Committee. The NHIN Coordinating Committee will review the task group's recommendation and make a final determination regarding the timeline for implementation of the Change. It will forward its determination to the NHIN Technical Committee in accordance with Section C.

C. Response

1. *Requests for Consultation.* Based upon its reasonable investigation, the NHIN Coordinating Committee shall forward a response to the NHIN Technical Committee with its analysis. The response shall state that it is made in an advisory capacity and is not a final determination of the NHIN Coordinating Committee. At such time as any final Change is submitted for evaluation under this policy, the NHIN Coordinating Committee shall undertake a formal, binding review.
2. *Development Changes.* At the conclusion of the response period established by the NHIN Coordinating Committee, the NHIN Coordinating Committee shall evaluate whether the Development Change is Material and a timeline for implementation. The decision of the NHIN Coordinating Committee regarding the Materiality of the Development Change and timeline for implementation shall be communicated to the NHIN Technical Committee.
3. *Compliance Changes.* Based upon responses from the Participants, legal counsel or other advisors, the NHIN Coordinating Committee shall provide input to the NHIN Technical Committee on the impact of the Compliance Change and the timeline for implementation.

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The NHIN Coordinating Committee shall forward to each Participant a copy of its response to the Technical Committee for all Changes. The Coordinating Committee may, but is not required, to send a copy of any response for Requests for Consultation. In some cases, the Coordinating Committee may feel that the proposed change that is the subject of a Request for Consultation is too preliminary to share with all Participants.

IV. Definitions:

Changes shall mean Developmental Changes and Compliance Changes.

DURSA: Data Use and Reciprocal Support Agreement

Emergent Specifications: Technical specifications that a select group of existing and/or potential Participants are prepared to implement in order to test the feasibility of the specifications, to identify whether the specifications reflect an appropriate Exchange capability, and assess whether the specifications are sufficiently mature to add as a production Exchange capability.

Material (as defined in the DURSA): [For purposes of a Developmental Change means the proposed change will] (i) have a significant adverse operational or financial impact on at least 20% of Participants; (ii) require at least 20% of Participants to materially modify their existing agreements with Participant Users or third parties; or (iii) require an amendment to [the DURSA].

All other capitalized terms, if not defined herein, shall have the same meaning as set forth in the DURSA.

VI. References:

DURSA

VII. Related Policies and Procedures:

Policy # 6, Information Handling.

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VIII. Version History:

	Date	Author	Comment
1	6/8/09	Randall E. Sermons	Original.
2	6/22/09	Randall E. Sermons	Remove language regarding failure of a Participant to respond to requests. Add paragraph regarding ability to gather information informally by verbal communication.
3	6/23/09	Randall E. Sermons	Per discussion with Mariann Yeager, Steve Gravely and Erin Whaley: Modify to make information collection activities more informal.
4	11/13/09	Randall E. Sermons	Modify structural components based on team review call held 11/10/09. Add concept of “Change Inquiry” permitting review and response of proposed changes under evaluation by the NHIN Technical Committee as part of its prioritization process.
5	11/17/09	Aaron Seib and Mariann Yeager	Captured feedback from 11/17 team review call.
6	11/20/09	Steve Gravely and Erin Whaley	Additional revisions based on feedback from 11/17 team review call.
7	12/23/09	Erin Whaley and Steve Gravely	Modified heading to reflect approval during 12/17/09 CC call.
8	5/26/10	Erin Whaley	Revised to reflect the process used by the CC, the concept of Emergence Specifications, and issues related to versioning
9	5/28/10	Mariann Yeager	Added clarifying revisions to proposed edits.
10	5/28/10	Erin Whaley	Revised based on feedback from the Policy & Technical Task Group.
11	7/15/10	Vernette Roberts	Updated heading to reflect approval during 7/15/10 CC call.